SCOTTISH EXECUTIVE

Health Department

GUIDANCE FOR THE SAFE USE OF CYTOTOXIC CHEMOTHERAPY

Background
Cytotoxic medicines are known to be potentially carcinogenic, mutagenic and are hazardous as defined by the Control of Substances Hazardous to Health Regulations 2002 (COSHH). Cytotoxic chemotherapy must be prescribed, dispensed, supplied and administered in accordance with the Medicines Act 1968.

Purpose
The attached guidance, endorsed by the Scottish Cancer Group, has been updated to reflect new knowledge, national guidelines and legislation on the Safe Use of Cytotoxic Chemotherapy and covers all care settings including the patient's home.

This circular and attachment supersedes HDL (2001)13.

Action
NHS Boards are required to ensure implementation of this guidance and to be able to demonstrate compliance in discharging their clinical governance responsibility.

It is the responsibility of NHS Boards and regional cancer networks to agree how best to take this forward.

Yours sincerely

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Guidance for the Safe Use of Cytotoxic Chemotherapy

March 2005

Guidance for the Safe Use of Cytotoxic Chemotherapy

This guidance was initially developed by a sub-group of the Scottish Oncology Pharmacy Practice Group with further multidisciplinary input from the regional cancer networks. Membership of the Groups is attached at Annex A.

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1 INTRODUCTION

Cytotoxic medicines are known to be potentially carcinogenic, mutagenic and teratogenic and are hazardous as defined by the Control of Substances Hazardous to Health (COSSH) Regulations. The risks to patients receiving cytotoxic chemotherapy are well documented and are balanced against clinical benefit. The risk to staff through occupational exposure is less clear however there is sufficient evidence to indicate that all necessary measures should be adopted to prevent exposure. Cytotoxic chemotherapy must be prescribed, dispensed, supplied and administered in accordance with the Medicines Act 1968.

HDL (2001) 13 aimed to summarise and augment currently available guidelines. This revision and update has the same purpose: to promote the safe use of cytotoxic chemotherapy. In recognition of the growing demand for treatment closer to and at home the scope of the guidance has been extended to include this – so called 'near patient chemotherapy'. It provides a framework for safe practice in the prescribing, preparation, administration and handling to minimise the risk to patients receiving cytotoxic chemotherapy and protect staff from occupational exposure to these hazardous medicines. The document should be used in conjunction with other relevant clinical guidelines when developing local or regional standards, policies and procedures.

This guidance should be available to all staff involved with receipt, storage, transport or disposal as well as those who prescribe, prepare, dispense or administer chemotherapy. Adherence to the guidance will minimise risk to all staff who handle cytotoxic chemotherapy.

2 SCOPE OF DOCUMENT

Patients of all age groups receiving cytotoxic chemotherapy for the treatment of cancer.

The use of cytotoxic medicines for non-cancer indications is outwith the scope of this document but is clearly applicable to all areas of practice where cytotoxic medicines are used.

Specific guidance on the handling of intrathecal cytotoxic medicines is to be found in the national guideline HDL (2004) 30.

3 GLOSSARY

ASSESS - Requires the auditor(s) to use their professional judgement in assessing whether the audit standard is complied with and, if not, attributing a non-compliance grade.

ASSIG – Scottish Aseptic Services Specialist Interest Group

AUDIT - A method by which those involved in providing services assess the quality of care. Results of a process or intervention are assessed, compared with a pre-existing standard, changed where necessary then reassessed.

CARCINOGEN - A substance that causes or can help to cause cancer.

CHEMOTHERAPY PROTOCOL - A treatment plan that includes one or more cytotoxic chemotherapy medicine. It is also often described as a chemotherapy regimen.

CHEMOTHERAPY PRESCRIPTION - The prescription is used to order chemotherapy medicines, authorise treatment and record their administration.

CLINICAL MANAGEMENT PLAN - A patient-specific document relating to supplementary prescribing, which relates to an individual patient. It is drawn up in conjunction with and agreed by the independent prescriber, supplementary prescriber and patient.

CLINICAL MANAGEMENT GUIDELINE - Clinical Management Guideline (CMG) promotes the equitable provision of high quality care by detailing appropriate management through all stages of the patient's journey – screening, diagnosis, staging, histopathology, investigations, radiotherapy, chemotherapy, supportive treatment and follow up.

CLINICAL WASTE - Clinical waste includes contaminated equipment used in the clinical area (needles, syringes etc) and body fluids and excreta (urine, faeces, blood, vomit). See also cytotoxic waste.

COSHH – Control of Substances Hazardous to Health Regulations 2002.

COURSE - This is the total number of chemotherapy treatments planned for one patient at a given stage in the clinical management plan. It is often spread over a number of weeks or months e.g. 6 cycles of chemotherapy at monthly intervals will make up one course.

CYCLE - Each individual chemotherapy treatment for a patient, the sum of which make up the course, e.g. 6 cycles of chemotherapy make up one course.

CYTOTOXIC – Chemicals that are directly toxic to cells preventing their replication or growth.

GLOSSARY CONTINUED

CYTOTOXIC CHEMOTHERAPY - A group of medicines active against cancer, but can also be used for non-malignant conditions. They are commonly classified according to their mode of action e.g. alkylating agents.

CYTOTOXIC WASTE - This includes all types of waste which could have been in contact with cytotoxic medicines, e.g. equipment, body fluids, used disposable personal protective equipment, as well as unused or part-used cytotoxic doses.

DISCUSS – An auditor questions relevant staff about the requirements of the standards.

DISPENSING - The activity of supplying a product in the appropriate form for a specific patient according to a prescription.

EPISODE - Each time a patient attends for treatment within a cycle.

EXAMINE - Relates to procedures, equipment, quality records and/or materials that need to be examined for content and validity. Procedures should be assessed for appropriateness and compliance with official guidelines. They should have been recently appraised, signed and, where appropriate, countersigned.

EXTRAVASATION – Leakage of an intravenous medicine from the vein.

GUIDELINE – A document containing best practice advice. May be used to develop specific local policies and procedures.

INDEPENDENT PRESCRIBER - An individual responsible for the initial clinical assessment of a patient and the formulation of a diagnosis. They are generally doctors and dentists.

INTRAVENOUS – Given into a vein by injection or infusion.

INTRATHECAL – Injection into the cerebrospinal fluid bathing the spinal cord and brain.

LICENSED FACILITY – A site is in possession of a Manufacturer's Specials Licence granted by the MHRA which allows the site to manufacture unlicensed medicines (specials).

MANAGED CLINICAL NETWORK (MCN) - A linked group of health professionals from primary, secondary and tertiary care, working in a co-ordinated manner, unconstrained by existing professional and NHS Board boundaries, to ensure equitable provision of high quality clinically effective services.

MHRA - Medicines and Healthcare products Regulatory Agency; the UK medicines licensing regulatory authority

MUTAGEN – A substance that can cause or increase the rate of genetic mutation.

GLOSSARY CONTINUED

NEAR MISS – An incident where the people involved came to no actual harm, but which could have had serious consequences.

OBSERVE - Relates to activities, which can be observed by auditor(s) and are representative of normal work practices.

OCCUPATIONAL EXPOSURE – Risks encountered from exposure to potentially or actually hazardous substances in the workplace.

PARENTERAL – Administration by some means other than the gastrointestinal tract or lungs. Generally taken to be by intravenous, subcutaneous or intramuscular injection.

PHARMACEUTICAL CARE – A systematic approach applied by a pharmacist to ensure that the patient gets the right medicines, in the right dose, at the right time and for the right reasons.

PHARMACEUTICAL CARE PLAN – A record of clinical pharmacy input to patient care. May be part of the multidisciplinary patient record, or stand-alone.

PHARMACEUTICAL VERIFICATION - A process by which a pharmacist ensures a prescription is clinically appropriate by reviewing relevant clinical parameters and all medicines being taken by the patient. The purpose is to identify, resolve and prevent medicine-related problems.

POLICY- A plan of action adopted by a group or organisation

PROCEDURE - A document giving detailed instructions on how to carry out a task, based on good practice.

PREPARATION - The manipulation of raw materials and components within the pharmacy to make a final product for dispensing or in anticipation of dispensing in accordance with a prescription.

QASIG - Scottish Quality Assurance Specialist Interest Group

RECORDS - A permanent written account of a process undertaken.

STANDARD OPERATING PROCEDURE (SOP) – A detailed written document, formally approved by a senior member of staff, which gives detailed instructions on how to carry out a task or use a piece of equipment to ensure that the operation is performed to a consistent standard.

SUPPLEMENTARY PRESCRIBER - An individual responsible for prescribing (working in partnership with independent prescriber) and assessing a patient's progress in accordance with the clinical management plan.

GLOSSARY CONTINUED

TERATOGEN - A substance that causes structural or functional abnormalities in the embryo or foetus.

VESICANT - A medicine, if extravasated, capable of causing pain, inflammation and blistering of the local skin, underlying flesh and structures leading to tissue death and necrosis.

WORKSHEET - A record that provides instructions for carrying out specific processes combined with space for details of individual operators, batch numbers etc to be inserted.

Number	Standard	Demonstration of Compliance
4 PRESCRIBING CYTOTOXIC CHEMOTHERAPY		
4.1 Clinical Management Guidelines		
4.1.1	A Clinical Management Guideline (CMG) is in place for all common tumour types.	Examine CMG
4.1.2	CMGs are prepared by a multi-disciplinary professional group representative of each of the professions likely to contribute to care under the protocol.	Examine CMG
4.1.3	All CMGs are approved by the managed clinical network and local clinical governance structures.	Examine CMG and approval process
4.1.4	The CMG is dated and has a review date after which the protocol is no longer valid.	Examine CMG and document control system
4.2 Chemotherapy Protocols		
4.2.1	Chemotherapy protocols are in place for all cytotoxic chemotherapy regimens detailed in CMGs. These can be paper-based or within an electronic prescribing system.	Examine protocols or electronic prescribing system

Number	Standard	Demonstration of Compliance
4.2.2	Chemotherapy protocols include clear and unambiguous statements on the following : • definition of the clinical condition being treated • all chemotherapy medicines to be given • dosing schedule for each medicine • route, method and duration over which the chemotherapy is to be administered • maximum cumulative doses where applicable • any pre-medication required • diluents & appropriate infusion volumes • hydration schedules (if required) • supportive therapy • relevant haematology and biochemistry results • any other tests that need to be performed before chemotherapy starts and during treatment • special precautions and contraindications to treatment • potential interactions and medications to be avoided • recommendations for treatment delays or dose reductions • expected toxicities • where relevant, reference should be made to policies for the management of side effects • advice on when patients should be referred for review by the consultant. • reference source(s)	Examine protocols or electronic prescribing system
4.2.3	There is a system in place for approving, reviewing and updating chemotherapy protocols or electronic prescription templates.	Examine local procedure
4.3	**General Prescribing Requirements**	
4.3.1	The initial decision to initiate cytotoxic chemotherapy is made by an accredited oncologist/haematologist or an appropriately trained and competent nominated deputy.	Examine local policy Examine patient record
4.3.2	Where there is a decision to give treatments not included in the CMG, sufficient information on the chemotherapy treatment, including evidence of safety and efficacy is available at the time of prescribing and pharmacy verification.	Examine patient record Examine pharmaceutical care plan (PCP)

Number	Standard	Demonstration of Compliance
4.3.3	The decision and the proposed management plan are documented in the patient's record.	Examine patient record
4.3.4	Only an appropriately qualified, competent practitioner (as defined by local policy) prescribes cytotoxic chemotherapy.	Examine patient record Examine local policy
4.3.5	Prescribing by supplementary prescribers is in accordance with the patient's clinical management plan.	Examine clinical management plan
4.3.7	The reason for using a treatment option outwith the CMG is recorded in the patient record.	Examine patient record
4.3.8	Staff prescribing chemotherapy have access to all relevant clinical data required to ensure safe and appropriate prescribing.	Examine patient record Observe
4.4	**Prescriptions and Documentation**	
4.4.1	Chemotherapy is prescribed on a standardised chemotherapy prescription or using an electronic prescribing system and complies with current legal requirements and local prescribing policy.	Examine chemotherapy prescription or electronic prescribing system
4.4.2	Prescriptions include: • the name of the chemotherapy protocol • all chemotherapy medicines to be given including protocol doses • intervals between cycles • maximum cumulative doses where applicable • route, method and duration of administration • where appropriate, diluents & infusion volumes • hydration schedules if required • pre-medication if required • appropriate supportive therapy • indication of concomitant radiotherapy where applicable • cycle number and date of administration • signature name of prescriber & date prescribed.	Examine prescriptions

Number	Standard	Demonstration of Compliance
4.4.3	The following patient specific information is documented: • name, date of birth, patient identification number, CHI number • height, weight & body surface area where relevant • diagnosis • relevant haematology and biochemistry results • any other relevant tests • calculated doses to be administered • indication of any dose modifications made	Examine prescription
4.4.4	Chemotherapy prescriptions for protocols outwith CMGs are checked and clinically approved by the patient's consultant or a senior specialist with appropriate experience.	Examine prescription Examine patient record
4.4.5	Patient chemotherapy prescriptions are readily accessible in patient's electronic or paper records for audit purposes.	Examine patient record
4.5	**Oral Cytotoxic Chemotherapy – Special Requirements**	
4.5.1	The prescribing of oral cytotoxic chemotherapy is carried out and monitored to the same standards as those for parenteral chemotherapy.	Examine patient record
4.5.2	All prescriptions for oral cytotoxic chemotherapy state the start date and duration of each treatment cycle.	Examine patient record and prescription
4.5.3	The planned course of treatment and follow up arrangements are recorded in the patient's notes and a review date set.	Examine patient record
4.5.4	Other than in exceptional and clearly defined circumstances prescribing remains the responsibility of the cancer specialist and, where appropriate, the supplementary prescriber.	Examine patient record Examine local policy
4.5.5	Oral chemotherapy drugs are not to be prescribed by repeat prescription.	Examine local policy Examine prescriptions

Number	Standard	Demonstration of Compliance
5	**PHARMACEUTICAL VERIFICATION, PREPARATION AND DISPENSING**	
5.1	**Pharmaceutical Verification**	
5.1.1	All prescriptions for chemotherapy must be verified by a suitably trained pharmacist in accordance with legislative requirements, national standards and guidelines.	Examine training records Examine care plans Observe
5.1.2	Chemotherapy protocols are readily available to pharmacy staff involved in the verification of cytotoxic chemotherapy.	Examine protocols
5.2	**Chemotherapy Preparation and Dispensing**	
5.2.1	All cytotoxic chemotherapy is supplied from a pharmacy controlled facility.	Examine local policy Observe
5.2.2	All cytotoxic chemotherapy is dispensed and labelled for the individual patient.	Observe
5.2.3	All cytotoxic chemotherapy requiring aseptic manipulation is prepared in accordance with legislative requirements, national standards and guidelines. The aseptic service is independently audited, by either: a. MHRA inspection within the 2 years prior to assessment visit (Licensed facility) b. Aseptic Services Specialist Interest Group (ASSIG) and the Quality Assurance Specialist Interest Group (QASIG) inspection within 2 years prior to assessment visit (Unlicensed facility) In either case, the organisation abides by the findings and there is an agreed action plan with priorities and timescales to address deficiencies.	Examine audit report and action plan
5.2.4	The dispensing of oral cytotoxic chemotherapy complies with relevant legislative standards, national standards and guidelines.	Examine Standard Operating Procedures (SOPs) Observe
5.2.5	Oral suspensions of cytotoxic medicines which do not have a UK product licence are purchased from a licensed specials manufacturer unless the pharmacy has specialised facilities for compounding such suspensions.	Examine records Examine facilities

Number	Standard	Demonstration of Compliance
6 ADMINISTRATION OF CYTOTOXIC CHEMOTHERAPY IN CANCER CENTRES OR UNITS		
6.1 General Administration Issues		
6.1.1	There is a local procedure and policy for the administration of cytotoxic chemotherapy.	Examine procedure and policy
6.1.2	There are designated wards and outpatient clinics where cytotoxic chemotherapy is administered.	Examine policy Observe
6.1.3	These designated areas are equipped to deal with any emergencies that may arise from the treatment.	Observe
6.1.4	Cytotoxic chemotherapy is commenced during normal working hours wherever possible when support services and expert advice are available.	Examine policy Discuss
6.1.5	The patient's condition is assessed prior to chemotherapy being commenced to ensure no significant deterioration has occurred since it was prescribed.	Discuss
6.2 Verification of Chemotherapy Treatment Prior to Administration		
6.2.1	Procedures exist for independent pre-administration checks by two suitably qualified practitioners to ensure: • correct patient • CHI number • date and time of administration • patient name on the cytotoxic chemotherapy and prescription form • drug name, dose, volume bolus/infusion, route of administration and administration rate is correct in relation to the prescription • expiry date and time on the item will not pass before administration is complete • steps to be taken if any discrepancies found • requirement for a second check.	Examine procedures Observe
6.2.2	The prescription is checked against standards 4.4.2 to 4.4.4.	Examine procedure Discuss
6.2.3	Both practitioners sign the appropriate sections of the administration document.	Examine documentation

Number	Standard	Demonstration of Compliance
6.3	**Intravenous Chemotherapy**	
6.3.1	Staff who administer intravenous cytotoxic chemotherapy are formally trained and competent in the administration procedures including the correct safe use of relevant vascular access devices.	Examine training records
6.3.2	Staff who administer cytotoxic chemotherapy are aware of immediate potentially dangerous side effects and ensure resuscitation equipment is readily available if required.	Discuss Observe
6.4	**Oral Chemotherapy**	
6.4.1	Procedures are in place for appropriate protective wear and disposal of single use medicine spoons/cups used for the administration of oral cytotoxic chemotherapy.	Examine procedure Observe
6.4.2	Once dispensed by pharmacy, tablets are not crushed, nor capsules opened, nor the medicine tampered with in any way. Local procedures provide information on the action to be taken if the patient is unable to take the medicine in the form presented.	Examine procedure
6.5	**Administration by Other Routes**	
6.5.1	Procedures are in place for cytotoxics administered by any route (other than intravenous, intrathecal or oral) within the organisation e.g. intramuscular, bladder instillation. Specific guidance on the handling of intrathecal cytotoxic can be found in the national guidance HDL (2004)30.	Examine procedures Discuss

Number	Standard	Demonstration of Compliance
7 EXTRAVASATION		
7.1 Minimising Risk of Extravasation		
7.1.1	Policy and procedures for the administration of chemotherapy include techniques which aim to minimise the risk of extravasation.	Examine policy Examine procedure
7.1.2	Staff who administer intravenous chemotherapy are aware of administration related risk factors which may compromise safe delivery of these medicines and document them.	Discuss Examine records
7.1.3	Patients are made aware of the potential risk and signs and symptoms of extravasation.	Examine procedure Discuss
7.2 Treatment of Extravasation		
7.2.1	A local extravasation procedure is in place to allow for the rapid treatment of chemotherapy extravasation injuries.	Examine procedure
7.2.2	Extravasation treatment kits and a copy of the extravasation procedure are readily available in the designated clinical areas where chemotherapy is administered.	Observe Examine procedure
7.2.3	Patients and their primary healthcare team/GP are kept fully informed of what treatment they will receive once an injury has occurred or is suspected.	Examine case notes
7.2.4	All chemotherapy extravasation injuries are recorded in patient case notes and a clinical incident report completed. The final outcome of treatment and degree of injury is also recorded.	Examine patient notes Examine procedure Discuss

Number	Standard	Demonstration of Compliance
8 RECEIPT, STORAGE AND TRANSPORTATION		
8.1	**Receipt and Storage of Cytotoxic Chemotherapy in Pharmacy**	
8.1.1	Cytotoxic medicines are received into the pharmacy department according to safe handling procedures.	Examine SOPs Observe
8.1.2	Cytotoxic medicines are stored securely and safely, and under the appropriate storage conditions within the pharmacy department. Temperature monitoring of storage areas is undertaken on a regular basis.	Examine facilities Examine records
8.1.3	Separate storage locations exist for cytotoxic products. These locations are clearly marked as being for cytotoxic medicines only.	Examine facilities
8.1.4	Staff receiving cytotoxic medicines into the pharmacy department are trained in the safe handling of these products.	Examine training records
8.2	**Transport of Cytotoxic Chemotherapy to Patient Areas**	
8.2.1	A procedure is in place to ensure cytotoxic medicines are transported safely and securely, and under the appropriate storage conditions.	Examine Procedure Observe
8.2.2	Staff transporting cytotoxic medicines are trained in the safe handling of these products.	Examine training records
8.3	**Receipt and Storage of Cytotoxic Chemotherapy in Patient Areas**	
8.3.1	Cytotoxic medicines are received into the patient areas according to safe handling procedures.	Examine Procedure Observe
8.3.2	Cytotoxic medicines are stored safely and securely, and under the appropriate storage conditions.	Examine facilities Examine records
8.3.3	Separate storage locations exist for cytotoxic medicines and are clearly marked as being for these products only.	Examine facilities
8.3.4	Staff accepting delivery of cytotoxic chemotherapy are trained in its safe, secure and appropriate storage.	Examine training records
8.3.5	A reconciliation record is required for the receipt of cytotoxic chemotherapy in patient areas.	Examine records

Number	Standard	Demonstration of Compliance
9 WASTE DISPOSAL		
9.1 Disposal of Unused/Part-used Chemotherapy and Contaminated Equipment		
9.1.1	A written local procedure for the disposal of all items contaminated with cytotoxic chemotherapy is available in all areas where it is used.	Examine procedure
9.1.2	The procedure clearly identifies the person with overall responsibility for the disposal of cytotoxic waste within the organisation.	Examine procedure
9.2 Disposal of Patient Waste		
9.2.1	There is a local procedure for the disposal and safe handling patient waste potentially contaminated with cytotoxic chemotherapy including information for patients.	Examine procedure Discuss
9.2.2	All staff handling patient waste have undergone training in safe handling procedure. This must include domestic staff involved in handling patient waste or cleaning the facilities used.	Examine training records

Number	Standard	Demonstration of Compliance
10 SPILLAGE OF CYTOTOXIC CHEMOTHERAPY		
	10.1 Dealing with Spillages	
10.1.1	Policy and procedures include safe practice which aims to minimise the risk of spillages.	Examine procedures
10.1.2	A COSHH risk assessment is undertaken for spillage involving cytotoxic medicines.	Examine risk assessment
10.1.3	Staff who transport or handle cytotoxic medicines or work in areas where these are stored or administered are trained in current local operating procedures for dealing with spillages.	Examine procedures Examine training records
10.1.4	Cytotoxic spillage kits are made available in all areas where cytotoxic medicines are prepared or administered.	Observe
10.1.5	Cytotoxic spillage kits are prominently displayed in clinical areas.	Observe

Number	Standard	Demonstration of Compliance
11 OUT OF HOURS		
	11.1 Service Provided	
11.1.1	The prescribing and preparation of elective cytotoxic chemotherapy outside routine working hours should be avoided. A local policy is in place detailing the circumstances where this is acceptable.	Examine policy Discuss

Number	Standard	Demonstration of Compliance
12 PROVISION OF CYTOTOXIC CHEMOTHERAPY OUTWITH CANCER CENTRES OR UNITS		
It may be appropriate to provide some cytotoxic chemotherapy outwith the Cancer Centre/Unit. This may allow patients to remain at home or near to home while receiving treatment. Treatment may be given in NHS premises e.g. GP surgery, community hospitals or in the patient's home. This is Near Patient Cytotoxic Chemotherapy (NPCC).		
12.1 Organisation		
12.1.1	The Centre/Unit offering Near Patient Cytotoxic Chemotherapy (NPCC) has a team responsible for the care of patients receiving NPCC. This should include the oncologist/haematologist, oncology nursing, oncology pharmacy and primary care representatives.	Examine policy Discuss
12.1.2	Cytotoxic chemotherapy protocols suitable for delivery in near patient areas are agreed by the NPCC team and approved by the Clinical Governance Committee and Drug and Therapeutics Committee (DTC) (or its Oncology Sub Group) of all NHS Board areas involved within the managed clinical network. Protocols with a high risk of immediate adverse effects requiring specialist care should be excluded.	Examine DTC documentation
12.1.3	Guidelines and procedures are in place to support NPCC. This includes: • administration of chemotherapy • prevention and management of extravasation • anaphylactic shock • management of neutropenic sepsis & other relevant medical emergencies • spillage • disposal.	Examine documentation
12.2 Patients and Premises		
12.2.1	The environment in which the NPCC is to be administered is suitable for the treatment being administered. This may include an assessment of the patient's home if home care is to be provided.	Observe
12.2.2	The required facilities and equipment, appropriate to the treatment being administered, is available e.g. spillage kit, extravasation kit, cytotoxic disposal bins, resuscitation and anaphylactic equipment.	Observe

Number	Standard	Demonstration of Compliance
12.2.3	The patient's condition is sufficiently stable, both physically and psychologically, to allow for the effective delivery of NPCC.	Examine patient records
12.2.4	The patient and any involved carers prefer NPCC to other available management options, having been fully involved in discussion of available treatment.	Examine documentation Discuss
12.3 Administration		
12.3.1	Procedures exist for pre-administration checks to ensure: • correct patient • date and time of administration • patient name & CHI number on the cytotoxic chemotherapy and prescription form • drug name, dose, volume bolus/infusion, route of administration and administration rate is correct in relation to the prescription • expiry date and time on the item will not pass before administration is complete • steps to be taken if any discrepancies found • requirement for a second check.	Examine procedures Observe
12.3.2	The prescription is checked against standards 4.4.2 to 4.4.4	Examine procedures Discuss
12.3.3	Patients and their main carers are capable of undertaking training to manage any infusion pumps or devices that may be required, and any expected effects of the cytotoxic agents.	Discuss
12.4 Support Staff		
12.4.1	Staff responsible for assessing the patient's condition, administering the NPCC and monitoring the patient have completed an accredited course in chemotherapy management and have demonstrated current competency to do this.	Examine training records

Number	Standard	Demonstration of Compliance
12.5	**Shared Care Arrangements**	
12.5.1	A shared-care protocol for each chemotherapy protocol suitable for NPCC provides information on the division of responsibility for patient care. The NPCC Team designates named staff responsible for : • assessment of patient and home environment for suitability • prescribing chemotherapy • verifying chemotherapy • preparing and dispensing chemotherapy • checking clinical parameters and blood counts before administration • assessing the patient is fit to receive chemotherapy • administration of the chemotherapy • delivery, storage and disposal arrangements, • possible side effects and how to manage adverse events • emergency contacts • follow up arrangements.	Examine protocols
12.5.2	When completed with individual information for a patient this becomes the Clinical Management Plan and includes review dates with the Centre/Unit.	Examine clinical management plans
12.5.3	The prescription (or copy) and the clinical management plan is available to the NPCC team, the GP and the staff administering the chemotherapy.	Observe Discuss

Number	Standard	Demonstration of Compliance
13 EDUCATION AND TRAINING		
	13.1 General	
13.1.1	Organisations ensure that education and training programmes are available to all staff who handle chemotherapy and/or its waste products appropriate to their needs/involvement. Training is available on an ongoing basis to ensure competencies are maintained.	Examine training programmes Attendance at training programmes
13.1.2	Staff who transport chemotherapy are trained in use of safe methods for transportation and action to be taken in the event of a spillage.	Examine training records Discuss
13.1.3	Domestic and auxiliary staff who clean areas where chemotherapy is handled are aware of procedures to minimise the risk of exposure to cytotoxic hazards.	Examine training records Discuss
13.1.4	Only staff who are suitably trained and competent should prescribe, prepare, dispense or administer cytotoxic chemotherapy.	Examine training records Discuss
13.1.5	All staff involved in the clinical care of patients receiving cytotoxic chemotherapy have appropriate knowledge and skills relevant to their field of practice.	Examine training records Discuss
13.1.6	An induction and training programme is provided for new members of staff.	Examine programme Examine training records
13.1.4	Rotational members of staff or those returning to work following an extended break e.g. maternity leave undertake a refresher programme on return.	Examine programme Examine training records

Number	Standard	Demonstration of Compliance
14 QUALITY AND RISK MANAGEMENT		
14.1 Clinical Governance		
14.1.1	Responsibility for the safe use of cytotoxic drugs rests with the Chief Executive of an NHS Board.	Examine policy
14.1.2	The Chief Executive may delegate responsibility for a particular locality to a head of service for chemotherapy, who is usually a consultant oncologist or haematologist.	Examine policy
14.1.3	The head of service for chemotherapy ensures that a robust structure is in place to allow the safe delivery of chemotherapy according to current legislation, national standards and guidelines	Examine policy
14.1.4	The head of service approves the local training arrangements, nominates named individuals who may prescribe or administer chemotherapy and maintains training records.	Examine policy
14.1.5	The head of service maintains a current list of protocols, and the localities in which these may be used.	Examine policy
14.1.6	The head of service liaises with the Drug and Therapeutics Committee and managed clinical networks to ensure consistency of standards across boundaries.	Examine policy
14.1.7	The head of service approves policies for the safe use of cytotoxic chemotherapy based on these guidelines and reviews these at least every three years.	Observe
14.1.8	For NPCC there is a system in place for detecting and reporting adverse events, incidents and near misses. These are notified to the NPCC team and through local clinical governance structures.	Examine documentation
14.1.9	All NPCC programmes include a system of quality assurance review. Regular audit of defined outcome measures such as patient acceptability, rate and type of adverse incident reports, and hospital visits saved are undertaken.	Examine documentation

14.2 Minimising Occupational Exposure

General Principles for Handling Cytotoxic Chemotherapy

Cytotoxic medicines are hazardous as defined by the Control of Substances Hazardous to Health Regulations 2002 (COSHH). COSHH regulations require organisations to ensure that employees working with carcinogenic substances are made aware of the risks and the circumstances under which they may be exposed to the carcinogen. All staff must handle cytotoxic medicines in such a way as to minimise exposure since little is known about the consequences of repeated exposure to small quantities of cytotoxic drugs. The main routes of potential exposure are via inhalation, absorption through the skin, ingestion through contaminated food or drinks and needle stick injuries.

As there is no defined maximum safe level of exposure or validated method of monitoring exposure, all staff must minimise exposure to cytotoxic chemotherapy by adhering to local policies and procedures and the principles in this guideline.

Number	Standard	Demonstration of Compliance
14.3	**Risk Assessment**	
14.3.1	All procedures involving handling of cytotoxic chemotherapy are risk assessed to determine that all appropriate risk control measures are in place.	Examine assessments
14.3.2	Staff involved in these procedures demonstrate an understanding of the risks posed by handling cytotoxic chemotherapy.	Discuss
14.3.3	Personal protective equipment suitable for the level of handling of cytotoxic chemotherapy is available to staff.	Examine equipment
14.3.4	Staff follow procedures for safe handling of cytotoxic chemotherapy.	Observe
14.3.5	Procedures are in place to allow the reporting of accidents, incidents or emergencies. This includes reporting of accidents such as spillage, clinical incidents and near misses. These reports are reviewed and the appropriate actions taken.	Examine procedures
14.3.6	Staff are informed, trained and supervised where appropriate, to ensure risk is minimised.	Examine training records

15 REFERENCES

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Reviewed the administration and extravasation aspects of the guidance

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REGIONAL CANCER NETWORKS GROUP B
Reviewed the “near patient chemotherapy” aspects of the guidance

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